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December 23, 1994

SUBJECT: RESULTS OF PANCREATIC CANCER STUDY

Dear Health Officer:

At the request of concerned citizens in Livingston, Montana, regarding the potential association between an apparently high incidence of cancer in the area and exposure to groundwater and airborne contaminants, the Montana Department of Health and Environmental Sciences (MDHES) and the Agency for Toxic Substances and Disease Registry (ATSDR) in 1990 analyzed death certificates and available medical records for the years 1980 to 1989.

This initial study, the "Investigation of a Cluster of Pancreatic Cancer Deaths, Livingston and Park County, Montana" (MDHES and ATSDR September 1992), reported a cluster of pancreatic cancer deaths from 1980 through 1989 in Park County, Montana. Through a review of death certificates and medical records, a statistically significant increase in age-adjusted pancreatic cancer mortality was found in white men in Livingston, Montana. A geographic plot of the residences of cases suggested a clustering of cases around the railroad repair and fueling facility. The study recommended a more rigorous epidemiologic investigation to further examine the potential association between pancreatic cancer and environmental factors in Livingston.

In December 1994, MDHES and ATSDR completed a follow-up state-wide pilot epidemiological pancreatic cancer study: "Pancreatic Cancer Mortality and Residential Proximity to Railroad Refueling facilities in Montana: A Records Based Case-Control Pilot Study" (ATSDR December 1994). This follow-up study investigated the potential association between pancreatic cancer and environmental contaminants at 12 Montana railroad refueling facilities. Researchers used information from death certificates to study pancreatic cancer deaths from 1980 to 1990 in Livingston, Missoula, Glendive, Laurel, Havre, Whitefish, Great Falls, Helena, Billings, Butte, Shelby and Glasgow.

The follow-up study was designed and performed within allowable budget and time constraints; consequently, it was limited in scope and contained uncertainties. Two important limitations of the study are the: 1) geographic location of an individual's

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residence may classify persons with little or no exposure in the same category with persons having extensive exposure to the contaminants of concern and 2) exposure was assigned based on the residence at the time of death.

In conducting the study, researchers combined death certificate information with the residential distance from each refueling site and found no statistical relationship between residential proximity to a refueling site and pancreatic cancer deaths. In addition, no association was found for pancreatic cancer deaths and employment in the railroad industry. Based on the follow-up study, ATSDR has described the original elevated pancreatic cancer cluster found in Livingston as anomalous and not unlike other anomalous cancer clusters found throughout the country.

For your information, I am enclosing a state-wide news release. If you have any questions or would like a copy of the report (reports are enclosed to health officers of the counties studied), please call me at (406) 444-1420 or Stephanie Prausnitz or Dr. Michael McGeehin at ATSDR (404) 639-6201.

Sincerely,

John Wadham

John Wadhams
Project Coordinator
BN Livingston site

enclosure

cc: Suzanne Brown, Park County Health Nurse
Randy Taylor, Park County Sanitarian
Park County Commissioners
Livingston City Manager

DRAFT REPORT - DO NOT CITE OR QUOTE

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY
ATLANTA, GEORGIA 30333

PANCREATIC CANCER MORTALITY AND RESIDENTIAL PROXIMITY TO RAILROAD REFUELING FACILITIES IN MONTANA: A RECORDS-BASED CASE-CONTROL PILOT STUDY

TECHNICAL ASSISTANCE TO THE
MONTANA DEPARTMENT OF HEALTH AND ENVIRONMENTAL SCIENCES
HELENA, MONTANA

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SUMMARY

The association between pancreatic cancer mortality and exposure to contaminants from railroad refueling facilities was investigated by the Montana Department of Health and Environmental Sciences (MDHES) and the Agency for Toxic Substances and Disease Registry (ATSDR). A previous investigation of a pancreatic cancer cluster suggested the possibility of such an association. A pilot study utilizing death certificate data was used to study pancreatic cancer mortality from 1980 to 1990 in the twelve populated areas where railroad refueling facilities are located in Montana. The study population included 471 case decedents and 881 controls matched on age, sex, time of death, and county of death. Through a review of death records and a spatial analysis of residential distance from the refueling station, no statistical relationship between residential proximity and pancreatic cancer mortality could be identified. In addition, no association was found for pancreatic cancer deaths and employment in the railroad industry as indicated on the death certificates.

INTRODUCTION

Hypothesis

The hypothesis tested by this study, stated as the alternative, is that cases of pancreatic cancer death were more likely to have lived near railroad refueling facilities than were similar controls dying of other causes. Specifically, this was a population-based case-control mortality study of pancreatic cancer based on information contained in death certificates.

Rationale for the Study Design

In 1992, ATSDR and MDHES completed an investigation of a reported cluster of pancreatic cancer deaths in Park County, Montana (1). The observed pancreatic cancer mortality among white males in Livingston, the principal city in Park county, during the years 1980 through 1989, was higher than expected when compared to the age-adjusted number of deaths expected on the basis of U.S. age and sex specific pancreatic mortality rates. The observed to expected ratio of pancreatic cancer deaths for white men in Livingston (14 cases) was 2.3 when adjusted for the U.S. population and 2.5 when adjusted for the Montana population, indicating that more than twice the number of pancreatic cancer deaths occurred in Livingston during that time period than were expected.

Although the cluster investigation could not determine the cause of this apparent increase in pancreatic cancer mortality, one possible hypothesis was that environmental exposure to toxicants related to the railroad refueling facility located in Livingston was responsible for the increase. For many decades, Livingston had been the site of a railroad repair and fueling station. Environmental data collected since 1985 have demonstrated soil contamination with volatile organic hydrocarbons in the area of the railroad yard and groundwater plumes of diesel fuel, dichloroethylene, trichloroethylene, and perchloroethylene emananting from the site. Sources of airborne toxicants may have included combustion products of coal, wood, or diesel fuel. An additional pilot study was then conducted to investigate whether residential proximity to a railroad refueling facility increases the risk of pancreatic cancer mortality.

Pancreatic cancer is suitable for a mortality study using death certificates because of the low survival rate and because patients with this catastrophic neoplasm are likely to seek and obtain medical care. Good correlation between pancreatic cancer mortality and pancreatic cancer incidence has previously been demonstrated for white men and women (2).

METHODS

Case Definition

A case was defined as any decedent in the 11 Montana counties with railroad refueling facilities with pancreatic cancer listed as a cause of death for the years 1980 through 1990. The 11 counties included Cascade, Dawson, Flathead, Hill, Lewis and Clark, Missoula, Park, Silver Bow, Toole, Valley and Yellowstone. Cases were ascertained through a review of the Montana Central Tumor Registry and review of death certificates. The following stepwise approach was taken to identify cases:

1) Persons listed as having pancreatic cancer in the Montana Central Tumor Registry from 1980 through 1990 were identified.

2) A death certificate was obtained for those individuals identified as having pancreatic cancer who died between January 1, 1980 and December 31, 1990.

3) An identified decedent was classified as a case when the county of residence listed on the death certificate was one of the eleven counties with railroad refueling facilities.

4) Additional cases, not included in the Montana Central Tumor Registry, were identified when the death certificate listed International Classification of Diseases (ICD-9) code 157 (pancreatic cancer) as the cause of death and the county of residence listed on the death certificate was one of the eleven counties with railroad refueling facilities.

Selection of Controls

Controls were selected from death certificates listing one of the 11 counties with railroad refueling facilities as the county of residence. Two controls were matched to each case. Controls and cases were matched on the following criteria: 1) gender; 2) age plus or minus three years; 3) date of death plus or minus one year; and 4) county of residence. Because the study population was overwhelmingly white (98%), controls were not matched on race. Controls were not selected by cause of death. The cause of death for the controls by ICD-9 codes is shown in Table 1.

Exposure Definition

Exposure was defined as residential proximity to the railroad refueling facility. Residence was based on death certificate information. For individuals who had a hospital or known nursing home listed, the next most previous address was identified and used. Concentric circles around the refueling facilities were drawn and each residence was categorized as being within a 0.5

mile, 1.0 mile , 1.5 mile, 2 mile, 3 mile, or greater than 3 mile radius from the site. Initial analysis considered a case or control as "unexposed" when the residence was greater than three miles from the facility, while individuals who resided closer to the facility were considered increasingly exposed. Subsequent analysis classified individuals as "exposed" if their residence was located within one mile of the railroad refueling facility, while those who had lived outside one mile were considered "unexposed." The environmental data necessary to accurately define and quantify potential chemical exposure at these sites is not available and therefore distance to the site is used as a proxy for individual exposure. Length of residence was not used since this information was not readily available nor recorded on the death certificate.

Sample Size Calculation

The sample size of 479 cases was calculated to be sufficient to detect a relative risk of 1.5, using a 1:2 case:control ratio, a power (1 - beta) of 0.80, and an alpha of 0.05 (two-sided test), as estimated using the formula described by Schlesselman (3).

Data Analysis

An extensive quality control program was in place for the data collection and data management process. All data from death certificates, as well as residential proximity to the facility, were entered into an electronic database. Proximity codes were assigned and entered by a geocoder; assignment and data entry were cross-checked by a separate worker. All other data were coded and entered directly from photocopied death certificates by two separate operators for comparison. Discrepancies were adjudicated.

The data were analyzed using conditional logistic regression analysis, which accounted for the matching (4). Maximum likelihood techniques were used to calculate odds ratios and 95% confidence intervals. Distance categories were included in the model as an ordinal variable with distance of > 3 miles being the referent group. Distance was also dichotomized at 1 mile and entered into the model as a categorical variable. The Wald test was used to derive the statistical inference of the odds ratio of the variable in the conditional logistic regression model.

Occupation in the railroad industry was added as a controlling factor to the model and was also assessed for an association with pancreatic cancer mortality. Occupation in the oil, paper, truck driving, mechanics/machine repair, tannery and chemical industries were assessed in the same fashion. Occupation was determined based on the participant's primary lifetime occupation as listed on the death certificate. Each occupation was entered

separately into the model as a dichotomous variable and the association with pancreatic cancer mortality assessed.
The modeling process for the analysis was simple. The dependent variable for the conditional logistic regression was case/control status. The main independent variable was residential proximity to the site. An additional independent variable representing occupation in the railroad industry was then added to the model and its association with pancreatic cancer evaluated. Due to the possible association between pancreatic cancer and sex (5), separate models for males and females were created.

RESULTS

Demographics

The study population included 479 cases and 881 controls. Of the original 958 controls selected for the two to one matched study design, 77 controls were excluded because they died in one of the study counties, but resided in a different county. As the cases were matched on age at death and gender, there were no significant differences in these variable between cases and controls. The mean age at death was 70 years and ranged from 25 to 100 years. The study population consisted of 49% females and 51% males. The racial composition of the study population was 98% white.

Occupation in the Railroad Industry

No significant difference between cases and controls was found regarding occupation in the railroad industry. 4% of the cases and 4.5% of the controls had railroad marked in the usual industry field of the death certificate (Table 2).

Exposure to Railroad Refueling Facilities

Exposure was defined by residential proximity to the railroad refueling facility. Initially, exposure was assumed to be greatest when the residence was within 0.5 miles of the facility, and decreased as distance increased to within 1.0 mile, 1.5 miles, 2.0 miles and 3.0 miles of the facility. A distance further than 3 miles was considered unexposed. No difference in residential distance from the facility could be found between cases and controls (p=0.33) (Table 3).

Conditional logistic regression analysis of the matched sets indicated no significant increase in the odds ratios for any exposed group classification when compared to the unexposed group, nor did the odds ratio exhibit any trend of increasing risk of pancreatic cancer death with decreasing distance (Table 4.)

For subsequent analysis, exposure was dichotomized at one mile: individuals residing within one mile of the site were defined as exposed while those outside of one mile were not. One mile was selected since it seemed a reasonable distance for deposition of airborne contaminants and the pilot study was conducted without any meteorologic or exposure information. Twenty one percent of the study population were categorized as exposed. There was no significant difference in the crude odds ratio for exposure in cases and controls (odds ratio: 1.06, 95% confidence limits at 0.79 and 1.41). Adjusting for occupation in the railroad industry, as marked on the death certificate, made no difference (odds ratio: 1.07, 95% confidence limits at 0.80 and 1.43). Employment in the railroad industry was not shown to be associated with pancreatic cancer mortality (odds ratio: 0.85, 95% confidence limits at 0.46 and 1.55) (Table 5). Separate analyses were performed to control for employment in each of the following industries: oil, paper, truck driving, mechanics/machine repair, tannery and chemical. Employment in these industries was not shown to be associated with pancreatic cancer mortality, but the numbers of individuals employed in each of the occupations was small and limited the precision of the estimates.

When the model was run separately by sex, the odds ratio for exposure was not significant for females (odds ratio: 0.98, 95%

confidence limits at 0.65 and 1.47) nor for males (odds ratio: 1.14, 95% confidence limits at 0.76 and 1.73).

Because Park county pancreatic cancer deaths investigated in the previous ecologic study (1) were used to generate the hypothesis tested in this study, the group of all counties excluding Park was analyzed. The odds ratio for exposure was not significant (odds ratio: 1.03, 95% confidence limits at 0.76 and 1.39).

In an effort to analyze a sample similar to the one used in the previous cancer cluster investigation (1), male residents of Park county were analyzed separately. That sample included 13 cases. The odds ratio for exposure was not significant in this group (odds ratio: 1.33, 95% confidence limits at 0.37 and 4.82). If exposure was defined as living in Livingston, as was suggested by the previous investigation, the OR was 1.77 (95% confidence limits at 0.39 and 8.03).

DISCUSSION

Summary of Findings

Based on the findings of this pilot study, residential proximity to a railroad refueling facility is not associated with pancreatic cancer mortality. The pilot study showed no difference in exposure between cases and controls, even when potential risk factors including age, sex, and railroad occupation were controlled for in the matching criteria or in the analysis. This finding is not inconsistent with the previous investigation, given the limitations of an ecological design and the lack of any attempt in the cluster investigation to define exposure.

Discussion of the literature

Case-control investigations of pancreatic cancer mortality risk described in the literature are inconclusive (8,9). A death certificate-based case-control pancreatic cancer mortality study conducted in Louisiana did not analyze specifically for railroad exposure, but found no significant association between occupation in the transportation industry and pancreatic cancer mortality (8). Non-significant increases in odds ratios were noted in the oil refining and paper industries. Those findings were not duplicated in a further study which used hospital-based cases and controls and which gathered information on smoking activity, dietary patterns, and lifetime occupational history (9). That study, while not specifically analyzing for railroad exposure, found-no significant association between transportation industry employment and pancreatic cancer mortality, nor were any significant elevated risks for pancreatic cancer found for truck driving or mechanics/machine repair.

Occupational epidemiological studies have suggested increased risks of pancreatic cancer mortality among oil refinery workers (10,11), tannery workers (12), employees exposed to cutting fluids and abrasives in metal machining and grinding (13), and chemical manufacturing employees exposed to DDT (14). The pilot study described in this report examined and found no effect of occupation in the oil, paper, truck driving, mechanics/machine repair, tannery or chemical industries.

Cohort studies of railroad workers or men exposed to diesel fumes found no occupational or diesel exposure effect on pancreatic cancer mortality rate (15,16,17). The standardized mortality ratio (SMR) for pancreatic cancer in Canadian males who retired from railway work was not statistically significantly elevated (15). A retrospective cohort pilot study of American railroad workers reported SMRs for all malignant neoplasms and for 11 selected specific cancers (16). No pancreatic cancer deaths were found in this cohort. A prospective study of American males found that those exposed to diesel fuel had no statistically significant increase in relative pancreatic cancer mortality risk compared to the unexposed (17). The study adjusted for age, smoking and other occupational exposures.

Other studies have searched for pancreas carcinogens and are reviewed elsewhere (18,19). Currently, beta-naphthylamine and benzidine are the only chemicals considered as potential pancreas carcinogens. Only tobacco smoking consistently emerges as a pancreatic cancer risk factor (18,19,20).

Study Limitations

Misclassification of exposure constitutes the single most important source of error in the pilot study. Assignment of exposure based on geographic location of an individual's residence as listed in a death certificate is a crude measure. This classification scheme can include the person who lives near the site and who has little or no exposure in the same category with persons having extensive exposure to contaminants. The exposure classification scheme also assumes that environmental exposure is consistent among the sites and within the exposure areas. This type of misclassification can strongly bias the odds ratio towards the null value, that is, find no association when there really is one (6). In this study, a 20% exposure misclassification of this type could cause a true odds ratio of 2.00 to appear as 1.06, the odds ratio found by this study.

Other potential sources of exposure misclassification include basing the exposure assignment on the residence at the time of death and neglecting other sources of exposure. Data for this study were gathered from available information found on the Montana death certificate, which does not record residential history. In 1990, approximately half the people in Montana had moved within the previous five years (7). This pilot study population, however, included predominantly older individuals with a mean age of 70 years, who may have been less mobile than the Montana population in general. Moreover, information regarding potential confounders or other risk factors, such as smoking, was not collected. Information on industry and occupation was less than ideal and length of residence was not evaluated.

Misclassification of disease status is also of some concern. However, given the unusually rapid course of this devastating malignancy, it is much less likely to be a major source of error than is misclassification of exposure. Of the 479 pancreatic cancer cases identified through death certificates, 321 (67%) were also identified in the State of Montana Central Tumor Registry.

Study Strength

This pilot study was conducted to address questions about pancreatic cancer mortality and exposure to railroad refueling facilities raised by a previous cancer cluster investigation (1). In that investigation, the pancreatic death rate was compared to national and state mortality rates and did not use controls. Unlike the previous investigation, this pilot study's strength lies in its case-control design, allowing for analysis of risk at the individual level. In the previous investigation, individual exposure status was not considered in the analysis. In this pilot study, residential proximity to the railroad refueling facility were determined on an individual level, serving as a surrogate for the individual's exposure status, which then could be linked back to the cause of death. Since multiple refueling facility sites were used, the results are more generalizable. Moreover, unlike in ecological studies, possible confounding of the association between residence and pancreatic caner mortality by sex or occupation was controlled to the extent possible.

CONCLUSION

Based on the findings of this study, residential proximity to railroad refueling facilities as determined at the time of death is not associated with pancreatic cancer mortality in Montana.

The limitations of death certificate data should be kept in mind, since information on occupation and other items provide only a fragmentary description of the work and residential histories; no data are available on length of residence nor risk factors such as smoking.

AUTHORS AND ACKNOWLEDGEMENTS

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TABLES

Table 1. Major causes of death for control population

Cause of death[*]	number	percent
Infectious and parasitic diseases	13	2
Neoplasms	157	18
Endocrine, nutritional and metabolic diseases	7	<1
Mental disorders	5	<1
Nervous system diseases	12	1
Circulatory system diseases	439	50
Respiratory system diseases	114	18
Digestive system diseases	29	3
Genitourinary system diseases	15	2
Musculoskeletal system diseases	3	<1
Certain conditions originating in the perinatal period	2	<1
Ill-defined conditions	52	6
Injury and poisoning	33	4

[*] As defined by the first ICD code listed on the death certificate

Table 2. Proportion of cases and controls employed in railroad industry

Cases employed in Railroad industry		Controls employed in Railroad industry	
number	percent	number	percent
19	4.0	40	4.5

Table 3. Residential proximity of cases and controls to railroad refueling facility

Proximity to facility (miles)	Cases		Controls	
	number	percent	number	percent
0-0.5	43	9	84	9
0.5-1.0	60	12	94	11
1.0-1.5	70	15	123	14
1.5-2.0	38	8	104	12
2.0-3.0	60	12	108	12
more than 3.0	208	43	368	42

Table 4. Conditional logistic regression model for exposure[*]
Pancreatic Cancer in Montana

Proximity to Facility	OR[†]	95% CI[¶]
less than 0.5 miles	0.88	0.58-1.35
between 0.5 and 1.0 mile	1.10	0.74-1.62
between 1.0 and 1.5 miles	0.99	0.69-1.42
between 1.5 and 2.0 miles	0.62	0.40-0.97
between 2.0 and 3.0 miles	1.02	0.70-1.48

[*] Reference group resides more than 3 miles from the facility
[†] Odds Ratio
[¶] 95% Confidence Interval

Table 5. Conditional logistic regression model for exposure[*] in entire study population and in study population subsets

Pancreatic Cancer in Montana

	OR[†]	95% CI[¶]
crude, entire study population	1.06	0.79-1.41
controlled for employment in railroad industry[§], entire study population	1.07	0.80-1.43
crude, females only	0.98	0.65-1.47
crude, males only	1.14	0.76-1.73
crude, all counties except Park	1.03	0.76-1.39
crude, Park county males only	1.33	0.37-4.82

[*] Exposure defined as residence within 1 mile of facility
[†] Odds Ratio
[¶] 95% Confidence Interval
[§] As marked on the death certificate